



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Stryker Corporation
Ms. Mairead Twomey
Sr. Staff Regulatory Affairs Specialist
4100 E. Milham Ave.
Kalamazoo, Michigan 49001

May 6, 2015

Re: K143540
Trade/Device Name: Stryker MIS Attachments and Cutting Accessories
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, and Their Accessories
Regulatory Class: Class II
Product Code: HBE, ERL
Dated: April 2, 2015
Received: April 3, 2015

Dear Ms. Twomey:

This letter corrects our substantially equivalent letter of May 1, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
And Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143540

Device Name

Stryker MIS Attachments and Cutting Accessories

Indications for Use (Describe)

The MIS Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the MIS Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/ Otorhinolaryngology; and Endoscopic applications.

Specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/ Anterior Skull Base/ Endoscopic/Transnasal/Transphenoidal, and Orthopedic Spine.

These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5

510(k) Summary

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510(k) Summary

510(k) Owner: Stryker Instruments
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Contact Person: Mairead Twomey
Sr. Staff Regulatory Affairs Specialist

Registration Number: 1811755

Date Summary Prepared: April 29, 2015

Trade Name(s): Stryker MIS Attachments and Cutting Accessories

Common Name: Surgical Drill Handpieces

Classification Data:

FDA Product Code	Device	Regulation Number	Class
HBE (Primary Code)	<i>Drills, burs, trephines, and accessories (simple, powered)</i>	21 CFR 882.4310	II
ERL (Secondary Code)	<i>Drill, surgical, ENT (electric or pneumatic) including handpiece</i>	21 CFR 874.4250	II

Predicate Device:

510(k) number	FDA Product code	Trade name	Manufacturer
K112593	ERL	Stryker® Consolidated Operating Room Equipment (CORE) System	Stryker Instruments

Indications for Use:

The MIS Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the MIS Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otorhinolaryngology; and Endoscopic applications.

Specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/Anterior Skull Base/Endoscopic/Transnasal/Transphenoidal, and Orthopedic Spine.

These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.

Device Description:

MIS Attachments and Cutting Accessories are prescription medical devices that are designed to provide an interface between a cutting accessory and a high speed motor. When used with a motor and a cutting accessory, the MIS Attachments are intended to cut, drill, ream, decorticate, shape, dissect, shave and smooth bone in a variety of surgical procedures including the following specialty areas: Neuro, Spine, ENT, Endoscopic and Orthopedics.

The Stryker MIS Attachments are available in straight, curved and angle styles and in two lengths – 13 cm and 16 cm.

Cutting accessories are single use, sterile devices which have a mount or notch machined at their proximal end and a head with a sharp cutting edge at their distal end. The MIS Cutting Accessories are designed to fit the corresponding MIS Attachments. The cutting accessories when used with a high speed drill and MIS Attachments are intended to cut, drill, ream, decorticate, shape, dissect, shave and smooth bone in a variety of surgical procedures.

**Performance Data
(Non Clinical Tests):**

The following verification tests were performed which demonstrate that the device meets the performance requirements under its indications for use conditions.

- Life, Functional and Graphics Testing of MIS Attachments
- Life Testing of Fluted and Diamond Bur Cutting Accessories
- Temperature Testing of Cutting Accessories
- Slippage Testing of Cutting Accessories
- Whip Testing of Cutting Accessories

- Chatter Testing of Cutting Accessories

Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the Stryker MIS Attachments and Cutting Accessories is sufficient for their intended use and support a determination of substantial equivalence.

Biocompatibility Tests:

Stryker MIS Attachments and Cutting Accessories are classified as external communicating devices: tissue/bone/dentin with limited patient contact (< 24 hours).

The biocompatibility evaluation was conducted in accordance with AAMI/ANSI/ISO ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and Guidance for Industry and FDA Staff, Use of International Standard ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,” dated April 23, 2013.

An overview of the Biocompatibility Testing performed is listed in Table 1. Results of testing validate that the subject devices are non-cytotoxic, non-sensitizing, a negligible irritant, non-toxic, and non-pyrogenic.

Table 1: Overview of Biocompatibility Testing

Tests Performed	Biocompatibility Test	Conclusions
Biocompatibility Testing	Cytotoxicity	Non-cytotoxic
	Sensitization	Non-sensitizing
	Irritation	Negligible irritant
	Acute Systemic Toxicity	Non-toxic
	Material Mediated Pyrogenicity (Attachments)	Non-pyrogen
	Bacterial Endotoxin Testing (Cutting Accessories)	Requirement met
	Colorant Leachables	Pass

Clinical Tests:

No clinical testing was deemed necessary for this 510(k).

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Table 2: Substantial Equivalence Table

Feature	Stryker® CORE (Predicate K112593)	Subject MIS (Attachments & Cutting Accessories)	Justification
Product Class	Class II	Class II	Identical
Regulation	21 CFR 874.4250 - Ear, nose, and throat electric or pneumatic surgical drill 21 CFR 882.4310 - Powered simple cranial drills, burrs, trephines 21 CFR 872.4120 - Bone cutting instrument and accessories	21 CFR 882.4310 - Powered simple cranial drills, burrs, trephines	Similar. The regulation of subject device falls within predicate cleared device.
FDA Product Code	ERL - Drill, Surgical, ENT (Electric or Pneumatic) including Handpiece HBE - Drills, Burrs, Trephines & Accessories (Simple, Powered) DZJ - Driver, Wire, and Bone Drill, Manual DZI - Drill, Bone, Powered	Primary: HBE - Drills, Burrs, Trephines & Accessories (Simple, Powered) Secondary: ERL - Drill, Surgical, ENT (Electric or Pneumatic) including Handpiece	Similar. The product code of subject device falls within predicate cleared device.
Intended Function	<ul style="list-style-type: none"> The predicate Stryker® MIS Attachments act as an interface between the high speed motors and the cutting accessories The predicate MIS attachments are intended as a location for the user to hold and grip the device system MIS Attachments and Cutting Accessories are intended to cut bone and used in the placement of screws, metal, wires, pins, and other fixation devices 	<ul style="list-style-type: none"> The subject Stryker® MIS Attachments act as an interface between the high speed motors and the cutting accessories MIS attachments are intended as a location for the user to hold and grip the device system MIS Attachments and Cutting Accessories are intended to cut bone and used in the preparation for the placement of screws, metal, wires, pins, and other fixation devices 	Identical
Patient Population	General	General	Identical

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Feature	Stryker® CORE (Predicate K112593)	Subject MIS (Attachments & Cutting Accessories)	Justification
Indications For Use	The Stryker® Consolidated Operating Room Equipment (CORE) System is intended for use in the cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to, dental, ENT (ear, nose, throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.	The MIS Attachments and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the MIS Attachments and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otorhinolaryngology; and Endoscopic applications. Specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/Anterior Skull Base/Endoscopic/Transnasal/Transphenoidal, and Orthopedic Spine. These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.	Similar. The intended use of all the devices identical; to cut bone. The specific indications that are being proposed for addition are a subset of already cleared indications for the predicate devices. Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
Contraindications	None known	None known	Identical
Conditions for Use	Attachments - Reusable	Attachments - Reusable	Identical
	Cutting Accessories - Single Use	Cutting Accessories - Single Use	Identical

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Feature	Stryker® CORE (Predicate K112593)	Subject MIS (Attachments & Cutting Accessories)	Justification
Patient Contacting Material- Attachment	304 Stainless Steel per ASTM A249	MIS 13 cm Attachment (Straight and Angled): 17-4 Stainless Steel per ASTM A564 with a color stripe composed of Uniglaze Epoxy Ink – Lilac PMS 265U.	Similar. Both the subject and the predicate are comprised of stainless steel. A color stripe has been added to the subject devices to aid system assembly.
	304 Stainless Steel per ASTM A249	MIS 16cm Attachment (Straight, Curved and Angled): 17-4 Stainless Steel per ASTM A564 with a color stripe composed of Uniglaze Epoxy Ink – Brown UGLZ-7145.	Biocompatibility, Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
Non Patient Contacting Material - Attachment	Bearing Lubricant Hub: Kluber Asonic GLY	Bearing Lubricant Hub: Kluber Asonic GLY	Identical
	Bearing Lubricant Rear Nose Tube: Chevron SRI Front Duplex Bearing: Chevron SRI	Bearing Lubricant Nose Tube (Front and Rear): Kluber Asonic GLY	Similar. Changed the nose tube bearing lubricant. The internal lubricant was modified for more durability during cleaning over device life. The lubricant is a non-patient contacting material and therefore out of scope for biocompatibility testing as per the ISO 10993 standard series. Verification and validation testing demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
	Retainer material Hub: Polyamide-imide Rear Nose Tube: 410 SST Front Duplex Bearing: 410 SST	Retainer material: Hub: Polyamide-imide Nose Tube, Front and Rear: 410 SST	Identical

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Feature	Stryker® CORE (Predicate K112593)	Subject MIS (Attachments & Cutting Accessories)	Justification
Color Band Identification	No	Yes Lilac PMS 265U Brown UGLZ-7145	Different. Added color band to aid system assembly and aid cutting accessory compatibility. Biocompatibility, Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
Patient Contacting Material- Cutting Accessories	Cutting Accessory Diamond Bur – Stainless Steel EN 10088-3 1.4112	Cutting Accessory Diamond Bur – Stainless Steel (440A) per ASTM F899	Similar. The change in stainless steel has been made to improve the manufacturability of the cutting accessories. Biocompatibility, Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
	Cutting Accessory Fluted Bur – M42 Tool steel per ASTM A600	Cutting Accessory Fluted Bur – M42 Tool steel per ASTM A600	Identical
Sterilization	Cutting accessories – supplied sterile, gamma irradiated	Cutting accessories – supplied sterile, gamma irradiated	Identical
	Attachment – End-user sterilized (provided non-sterile) IFU has instructions on how to sterilize (ETO, gas plasma, gravity displacement, moist heat)	Attachment – End-user sterilized (provided non-sterile) IFU has instructions on how to sterilize (ETO, gas plasma, gravity displacement, moist heat)	Identical
Sterility Assurance Level	Attachments: 10 ⁻⁶	Attachment: 10 ⁻⁶	Identical
	Cutting Accessories: 10 ⁻⁶	Cutting Accessories: 10 ⁻⁶	Identical
Shelf Life	Diamond Cutting Accessories = 5 years	Diamond Cutting Accessories = 5 years	Identical
	Fluted Cutting Accessories Tool Steel = 3 years	Fluted Cutting Accessories Tool Steel = 3 years	
	Attachments –Not applicable as these are reusable devices	Attachments – Not applicable as these are reusable devices	Identical

Traditional 510(k) Submission

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510(k) Summary, Rev 02

Stryker MIS Attachments and Cutting Accessories

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Feature	Stryker® CORE (Predicate K112593)	Subject MIS (Attachments & Cutting Accessories)	Justification
Packaging Configuration	Attachments - Retention Insert in a corrugated folder carton	Attachments - Retention Insert in a corrugated folder carton	Identical
	MIS Cutting Accessories - tube in a sealed chevron style pouch sterile barrier system	MIS Cutting Accessories - tube in a sealed chevron style pouch sterile barrier system	Identical
Attachment to Motor Locking Mechanism	SD/PD style interface	SD/PD style interface	Identical
Nose Tube Style	Straight, Curved	Straight, Curved, Angled	Different. The addition of the Angled MIS Attachment to the product line is to provide a wider range of product offerings. Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
Cutting Accessory Locking Mechanism	Friction collet lock	Positive collet locking notch	Different. The change of notch is to improve the retention of the cutting accessory in the MIS attachment. Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
Shank of the Cutting Accessory	Single shank configuration	Dual shank configuration	Different. The change from a single shank configuration to a dual shank configuration is to increase the yield strength of the cutting accessories. Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.

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Feature	Stryker® CORE (Predicate K112593)	Subject MIS (Attachments & Cutting Accessories)	Justification
Cutting Accessory Head Style Offering	Round, Diamond, Match Head	Round, Diamond, Match Head	Identical
Cutting Accessories Diameter Head Size	1.5 mm - 3.5 mm	1.5 mm - 5.0 mm	Different. The addition of head sizes to the MIS Cutting Accessory range is to the product line is to provide a wider range of product offerings. Verification and Validation Testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
Cutting Accessory Length	One length 15.69 cm	Two lengths 13 and 16 cm	Similar. The lengths of the Cutting Accessories are designed to fit the corresponding MIS Nose Tube. Verification and Validation testing has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.
Motor power supply	Electric and Pneumatic	Electric and Pneumatic	Identical
Speed	5000-75000 rpm	5000-75000 rpm	Identical
Pneumatic Pressure Recommendation	120 psi (pounds per square inch)	120 psi (pounds per square inch)	Identical
Source of Activation	Handswitch and Footswitch	Handswitch and Footswitch	Identical

Conclusion / Substantial Equivalence (SE) Rationale

The subject Stryker® MIS Attachments and Cutting Accessories have the same intended use, and similar indications, technologies, characteristics, and principals of operation as the predicate devices. The Stryker® MIS Attachments and Cutting Accessories have a similar safety and effectiveness profile as the legally marketed predicate devices.